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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,996	10/17/2003	Lothar Steidler	2676-6096US	1934
24247	7590	07/17/2008	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			SLOBODYANSKY, ELIZABETH	
			ART UNIT	PAPER NUMBER
			1652	
			NOTIFICATION DATE	DELIVERY MODE
			07/17/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

## Office Action Summary

Application No.

10/687,996

Applicant(s)

STEIDLER, LOTHAR

Examiner

Elizabeth Slobodyansky, PhD

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

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- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-17, 21-32 and 34-64 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/7/08; 1/28/08; 3/27/08.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The amendment filed January 28, 2008 amending claims 1, 2, 5, 12, 13, 21, 22, 24, 31-34, 37, 43, 44, 46, 48, 55, 56, 62 and 63 and adding claim 64 have been entered.

Claims 1-64 are pending. Claims 11 and 18-20 have been previously withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-31 and 43-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is confusing because it recites "a means for encoding an inactive *Lactococcus* thymidylate synthase". It is unclear what is defined by the "means" other than structure, i.e., a nucleic acid encoding an inactive *Lactococcus* thymidylate synthase.

Claim 22 is confusing as reciting "strain of *Lactococcus* bacterium comprises a thymidylate synthase gene selected from the group consisting of SEQ ID NO:3 and SEQ ID NO:5". The specification teaches that SEQ ID NO:5 is a mutant version of SEQ ID NO:3 (page 11, [0036]).

Claim 31 is confusing as reciting "wherein said nucleic acid encoding an inactive *Lactococcus* thymidylate synthase comprises a nucleotide sequence selected from the group consisting of SEQ ID NO:3 and SEQ ID NO:5". At least SEQ ID NO: 3 encodes an active *Lactococcus* thymidylate synthase while SEQ ID NO:5 is a mutant version of SEQ ID NO:3 (page 11, [0036]). It is unclear whether SEQ ID NO:5 encodes an active or an inactive thymidylate synthase.

Claims 43 and 44 are confusing as reciting "a defect in said thymidylate synthase gene". It is impossible to know the metes and bounds of the claims without knowing what kind of defect is introduced.

Claims 62 and 63 are confusing as reciting "An improvement in an isolated *Lactococcus* bacterium ..., wherein the improvement comprises altering SEQ ID NO: 3 or SEQ ID NO:5 (a *Lactococcus* thymidylate synthase gene) ... to encode an inactive thymidylate synthase". It is unclear what constitutes the improvement and it is the improvement.

Claims not specifically discussed herein are rejected as dependent from the rejected base claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12-17, 21, 23-30, 32 and 34-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson et al.

Nilsson et al. (WO 00/01799, form PTO-1449 filed March 27, 2008) teach inactivation of the chromosomal *thyA* gene in *Lactococcus lactis* strain MBP71 (pages 19-22). It was shown be chromosomally (not plasmid) encoded (page 20). Said gene comprises at least 100 contiguous nucleotides that are at least 90% identical to a region of SEQ ID NOs: 1 and 2. It is noted that claim 1 does not require for "at least 100 contiguous nucleotides" to be at least 90% identical to SEQ ID NOs: 1 and 2 but only to a region of SEQ ID NOs: 1 and 2. A region can be construed as any two nucleotides.

### ***Allowable Subject Matter***

Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments filed January 28, 2008 have been fully considered but they are not persuasive.

With regard to the 112, 2nd paragraph rejection of claim 21, Applicant argues that "'means for", as recited in claim 21, has a specific definition attributed to it by

paragraph six of 35 U.S.C. § 112; to wit: "[a]n element in a claim for a combination may be expressed as a means or a step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claims shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." Thus, the recitation of "means for" is not indefinite, it has the precise definition provided by paragraph six of 35 U.S.C. § 112 (see M.P.E.P. §§ 2181-2186)" (Remarks, page 15). This is not persuasive because it is unclear what else other than a structure is encompassed by the claim.

The 112, 1<sup>st</sup> paragraph written description and enablement rejections are withdrawn in view of Applicant's arguments and showing the alignment of thymidylate synthases in *Lactococcus* (pages 17-18).

The rejections not reiterated herein are withdrawn in view of the amendment.

### **Conclusion**

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on March 27, 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed, PhD can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth Slobodyansky/

Elizabeth Slobodyansky, PhD  
Primary Examiner  
Art Unit 1652

April 26, 2008



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|--|---|
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/Elizabeth Slobodyansky/

Elizabeth Slobodyansky, PhD  
Primary Examiner  
Art Unit 1652

April 26, 2008